SUPPORTING STATEMENT FOR
CLIA WAIVER APPLICATIONS
0910-0598

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Abstract:
The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services before accepting materials derived from the human body for laboratory tests (42 CFR 493.1) http://edocket.access.gpo.gov/cfr_2004/octqtr/pdf/42cfr493.15.pdf

Laboratories that perform only tests that are "so simple and accurate as to render the likelihood of erroneous results negligible" may obtain a certificate of waiver (42 CFR 493.15(a) and (b). (see above link). In the Federal Register of April 27, 2004 (69 FR 22849), the Secretary delegated to FDA the authority to determine under CLIA whether particular tests (waived tests) are "simple" and have "an insignificant risk of an erroneous result". http://frwebgate1.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=435247111040+2+2+0&WAISaction=retrieve

Device manufacturers will submit to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application).

On January 30 2008, FDA published a guidance, titled, "Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices". http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm079632.htm

FDA is requesting approval of the following information collections:

Reporting - Manufacturers will prepare the CLIA waiver application, including study results, device description, hazard analysis information and labeling, and quick reference instructions.

Recordkeeping - Manufacturers will conduct studies to test the device proposed for waiver at external clinical sites representative of users to which the device will be marketed. Manufacturers will compare these results to those obtained by a reference (well-validated) method.

This information is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

FDA will use information from the information collection provisions to determine whether a particular test is "simple" and has "an insignificant risk of an erroneous result." FDA's evaluation of the test will determine whether FDA will categorize the device as CLIA waived. .

Respondents are from the private sector, specifically manufacturers of in vitro diagnostic devices applying for "CLIA waived" designation of a device.

3. Use of Improved Information Technology and Burden Reduction

Manufacturers will have the option of submitting the waiver application or any part of the application electronically, whenever possible, although this was not addressed in the guidance document. Typically all manufacturers submit electronic copies in place of duplicate copies, and also submit electronically those sections of the application that contain data. These portions of the application account for approximately 50% of each application. In the past year, one manufacturer submitted an application that was entirely electronic.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency responsible for the collection of information associated with the CLIA waiver application. The Secretary of Health and Human Services delegated this responsibility to FDA on April 27, 2004. No similar data is available from other sources.

5. Impact on Small Businesses or Other Small Entities

All respondents are businesses. Typically CLIA waiver applications are submitted by mid-sized (greater than 100 employees) or smaller companies. This information collection therefore has an impact on small entities. FDA aids small business in dealing with the recommendations for waiver application by providing guidance and information through the Center for Devices and Radiological Health's Division of Small Manufacturers, International, and Consumer Assistance. In addition to participating or conducting conferences, workshops, and seminars for small firms, DSMICA staff is available to respond to questions via a toll-free telephone number. Manufacturers may also contact the Office of In Vitro Diagnostic Device Evaluation and Safety for questions.

6. Consequences of Collecting the Information Less Frequently

The information collection is submitted no more than one time per device. CLIA waiver applications are submitted occasionally, specifically by manufacturers requesting CLIA waived categorization for a diagnostic test. There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection is consistent with the guidelines prescribed in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the FDA

In the Federal Register of October 20, 2009 (74 FR 53750) FDA solicited comments on the collection of information. No comments were received. The comment period ended December 21, 2009). http://edocket.access.gpo.gov/2009/pdf/E9-25177.pdf

CDRH (including both OIVD and the Division of Biostatistics) maintains dialogue with industry representatives (Advamed), regarding development of additional options regarding study design and data analysis approaches for certain devices to demonstrate they are suitable candidates for waiver. The Advamed contact for these dialogues is:

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Associate Vice President, Technology and Regulatory Affairs
Advanced Medical Technology Association (AdvaMed)
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Suite 800
Washington, DC 20004
202.434.7267 (w)
202.413-8216 (c)

9. Explanation of Any Payment or Gifts to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

FDA treats all information related to CLIA applications as confidential. Confidentiality is not addressed in the guidance document.

11. Justification for Sensitive Questions

A CLIA waiver application does not include questions pertaining to sexual behavior, attitude, religious beliefs, or to other matters commonly considered private or sensitive in nature.

12. Burden Estimate (Total Hours and Wages)

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection as follows:

TABLE 1. – ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours	Operating and Maintenance Costs
42 CFR 493.15(a) and (b).	40	1	40	780	31,200	$50,200

TABLE 2. – ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours	Operating and Maintenance Costs
42 CFR 493.15(a) and (b).	40	1	40	2,800	112,000	$16,000

[1] No capital costs are associated with this collection of information.

FDA expects that 40 manufacturers may submit one CLIA waiver application in any given year. The time required to prepare and submit a waiver application, including the time needed to assemble supporting data, averages 780 hours per waiver application for a total of 31,200 hours for reporting. FDA estimates that the recordkeeping burden per respondent is 2,800. The number of hours (2800) times the number of respondents (40) results in a total of 112.000 recordkeeping hours. These estimates are based on an agency analysis of the type of study recommended in the guidance. The total number of reporting and recordkeeping hours is 143,200 hours. FDA bases the burden on an agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests.

12 b. Annualized Cost Burden Estimate

As noted above, the total number of reporting and recordkeeping hours is 143,200. Multiplying this by an average rate of $43 per hour yields an estimated annual cost to respondents of $6,156,000. These rates are an estimate of an average of salaries of all individuals involved in the clinical study. This is tabulated below:

Type of Respondent	Total Burden Hours	Averaged Hourly Wage	Total Respondent Costs for Wages
Manufacturer	143,200	$43	$6,156,000

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

The total operating and maintenance cost associated with the waiver application is estimated at $66,200. The cost consists of specimen collection for the clinical study (estimated $23,500); laboratory supplies, reference testing and study oversight (estimated $30,000); shipping and office supplies (estimated $6,000); and educational materials, including quick reference instructions (estimated $10,000).

14. Annualized Cost to the Federal Government

FDA estimates that it spends an average of 6 full time equivalents (FTEs) reviewing and processing waiver applications. An average full time equivalent employee is projected to cost FDA $122,100, which consists of the employee's salary and overhead. The burden imposed upon the government for this information collection is $732,600. (These updates are based on tables posted at http://www.opm.gov/oca/06tables/pdf/gs.pdf)

15. Explanation for Program or Changes or Adjustments

No changes have been made to the guidance. The estimate of burden hours is unchanged. The estimate of costs has been updated for estimates of inflation.

16. Publication and Tabulation Dates

FDA does not intend to publish or tabulate the results of this information collection.

17. Display of OMB Approval Date

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exception to Certification for Paperwork Reduction Act Submissions

FDA is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions.